

J. Delescluse
Y. Dinet

Division of Dermatology,
Centre Hospitalier César de Paepe,
Brussels, Belgium

Nickel Allergy in Europe: The New European Legislation

Key Words

Contact dermatitis
Nickel allergy
European legislation

Abstract

A new directive from the European Union (EU) will restrict the use of nickel from 1996 on. The consequences of this directive in the EU are considered.

Nickel is the main cause of metal allergy in Europe [1]. The incidence of nickel sensitivity is higher in women than in men [2-6]; however, the incidence recorded in a clinic or in a patch test clinic is determined by the relative number of females tested, and this may falsify our concept of nickel allergy [7]. The incidence of nickel allergy rises to 20% in some series [8-10]. The incidence of nickel dermatitis in one of the states of the Union varied with the total imports of nickel during and after World War 2 [11], which implies that nickel in the environment causes the incidence and the prevalence of nickel allergy. In Finland, 4.5% of the general population were found to be nickel allergic, i.e. 8% of women and only 0.8% of men [12]. The incidence of nickel dermatitis is still rising [13], mainly caused by cheap jewelry and nickel in clothing accessories.

In extra-European countries, the incidence of nickel allergy is similar [14-16] to that observed in our nation.

The prevalence of nickel allergy is between 8 and 10% [13] and rises to 27% in hairdressers [17].

Jeans accessories and cheap jewelry are now the main cause of nickel allergy [18]. Ear piercing, and the wearing of cheap nickel earrings is probably the main cause of nickel sensitization in girls [19, 20]; this has not yet been the case for boys [21], although no concluding results have been drawn from various studies [1, 21]. Although Finland is not (yet) a member of the EU, this could well become a fact from 1995 on, and the European Council, as well as the European Parliament have considered taking measures considering the use of nickel in everyday life.

The European Council, the executive authority of the European Union, seated in Brussels, and the European Parliament, the legislative authority, seated in Brussels and Strasbourg, have decided to send a directive to all state members of the European Union. This directive will be automatically in application in all state members and candidate-members of the EU. Details concerning the date of application of this directive will be given below.

This directive derives directly from the Danish Law [22]. Denmark is one of the latest members of the European Union, and has an advanced legislation concerning environment. The ambition of the European Union is to take the best of all local legislations, and to integrate it in an European Legislation.

The directive has received the full support of the European Society of Contact Dermatitis.

A common position of the European Council and the European Parliament has been arrested on March 4th, 1994, despite the intense lobbying of all European nickel factories. This common position concerns the 14th modification of the directive of 1976 concerning the limitation of dangerous preparations and substances.

A summary of this directive follows, but the whole legislation is easily available in all of the official languages of Europe at the address of the European Parliament: rue Belliard 97, B-1130 Brussels, Belgium [23] (Danish, Dutch, French, German, Greek, Irish, Italian, Portuguese, Spanish).

Summary of the Directive Concerning Nickel

(i) The use of nickel is forbidden in all objects introduced, temporarily or not, in pierced ears and in other parts of the human body, during the epithelialisation of the wound provoked by perforation.

(ii) The use of nickel is also forbidden in all products placed in direct and prolonged contact with the human skin, such as earrings, fantasy jewelry, rings, watches, clothing accessories.

(iii) The use of nickel is also forbidden in all accessories which are plated with another metal, except if the coat is as strong as to allow a liberation of nickel of less than 0.5 $\mu\text{g}/\text{cm}^2/\text{week}$ during a normal use of 2 years minimum.

At the executive level, the directive has been accepted by all states, except Italy. At the legislative level, the directive has been accepted, despite many attempts of the powerful nickel lobby.

A last attempt, called 'declaration of reject intention' was turned down on April, 26th, 1994 [24]. The publication of the directive in the Official European Journal is foreseen for August 1994. Each State of the European Union will then have 6 months to incorporate the directive in its own legislation.

One year after the publication of the directive (i.e. August 1995), the industry and importing companies will be forbidden to use nickel.

Eighteen months after the publication (i.e. in February 1996), nickel-containing products will be forbidden in all shops. This means that any dermatologist, or dermatological society, will be able to introduce a claim to the European Court in Luxemburg if such an object is found to cause any damage to a patient, and that the responsible industry or company might have to indemnify patients developing nickel contact sensitivity.

This constitutes an important step for the protection of the population. Moreover, the concentration of 0.5 $\mu\text{g}/\text{cm}^2/\text{week}$ is exactly the one which can be detected by the dimethylglyoxime test, and this makes it easy for all dermatologists to determine whether an object is, or is not, permitted.

This law is already in application in Denmark, and its incidence on nickel dermatitis will certainly be followed with interest by all dermatologists.

So the European legislation will restrict the use of nickel in our 12 (soon 16?) states. It is certainly a crucial step towards an efficient prevention of nickel allergy.

References

- Schollhammer M, Guillet MH, Guillet G: Nickel et peau. *Ann Dermatol Vénéreol* 1994; 121:338–345.
- Bonnevie P: Actiologie und Pathogenese der Eczemkrankheiten. Copenhagen, Busck, 1939.
- Calnan CD: Nickel dermatitis. *Br J Dermatol* 1956;68:229–236.
- Fregert S, Hjorth N, Magnusson B, et al: Epidemiology of contact dermatitis. *Trans St John's Hosp Dermatol Soc* 1969;55:17–35.
- Menné T, Bachmann E: Permanent disability from hand dermatitis in females sensitive to nickel, chromium and cobalt. *Dermatosen Beruf Umwelt* 1979;27:129–135.
- Wilkinson JD: Nickel allergy and orthopaedic prostheses; in Maibach HI, Menné (eds): *Nickel and the Skin: Immunology and Toxicology*. Bâton Rouge, CRC Press, 1989, pp 187–193.
- Magnusson B, Blohm SG, Fregert S, et al: Routine patch testing. II. Proposed basic series of test substances for Scandinavian countries and general remarks on testing technique. *Acta Derm Venereol (Stockh)* 1966;46:396–400.
- Angelini G, Vena GA, Fiordalisi F, et al: Allergia da contatto al nickel. *Riviera epidemiologica e clinici. G Ital Dermatol Venereol* 1986; 121:121.
- Husain SI: Contact dermatitis in the West of Scotland. *Contact Dermatitis* 1977;3: 327–332.
- Oleffe J, Nopp-Oger MJ, Achten G: Batterie européenne des tests épicutanés: Bilan de 30 observations. *Berufsdermatosen* 1972;20:209.
- Marcussen PV: The rise in incidence of nickel sensitivity. *Br J Dermatol* 1959;71:97–101.
- Peltonen L: Nickel sensitivity in the general population. *Contact Dermatitis* 1979;5:27–32.
- Menné T, Christophersen J, Green A: Epidemiology of nickel dermatitis; in Maibach HI, Menné T (eds): *Nickel and the Skin: Immunology and Toxicology*. Bâton Rouge, CRC Press, 1989, pp 109–115.
- Kanan MW: Contact Dermatitis in Kuwait. *J Kuwait Med Assoc* 1968;3:129.
- Olumide YM: Contact dermatitis in Nigeria. *Contact Dermatitis* 1985;12:281.
- Sugai T, Takagi T, Yamamoto S, et al: Age distribution of the incidence of contact sensitivity to standard allergens. *Contact Dermatitis* 1979;5:383–388.
- Van Der Burg CKH, Bruynzeel DP, Vreeburgh KHH, et al: Hand eczema in hairdressers and nurses: A prospective study. I. Evaluation of atopy and nickel hypersensitivity at the start of apprenticeship. *Contact Dermatitis* 1986; 275–279.
- Menné T, Borgan Ø, Green A: Nickel allergy and hand dermatitis in a stratified sample of the Danish female population. *Acta Derm Venereol (Stockh)* 1982;62:35–41.
- Christensen OB, Møller H: Nickel allergy and hand eczema. *Contact Dermatitis* 1975;1: 129–135.
- Christophersen J, Menné TM, Tanghof P, et al: Clinical patch test data evaluated by multivariate analysis. *Contact Dermatitis* 1989;21: 291–299.
- Cronin E: Clinical prediction of patch test results. *Trans St John's Hosp Dermatol Soc* 1972;58:153–162.
- Menné T, Rasmussen K: Regulation of nickel exposure in Denmark. *Contact Dermatitis* 1990;23:57–58.
- Parlement Européen: Documents de séance en langue française. Position Commune réf. COD-456. Parlement Européen, éd. 1994-03-09.
- Parlement Européen: Documents de séance en langue française. Proposition de déclaration d'intention de rejet réf. A3-0279/94. Parlement Européen, éd. 208-796/déf.